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#### **DETAILED ACTION**

# Specification

1. The amendment to the specification has been received on 6/21/11 and accepted.

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 4. Claims 1, 3, 4, 7, 8, 10-12,14-16, 20, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beane et al. (US 2002/0022762 A1) in view of Gunday (US 7453490 B2).
- 5. Regarding claim 1, Beane teaches an apparatus comprising a heat conducting tube [114] capable of receiving said distal portion, and a heating element [120] thermally coupled to said tube, and an absorbent porous element [116], capable of being cotton

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[par. 0061], within or at the distal end of said tube for cleaning the distal end of the optical instrument. While Beane is silent to using the porous element as a whitening element, Gunday teaches the use of white gauze or cloth (absorbent porous materials) for white balancing is commonly known in the art [col. 11, II. 16-19]. Although Gunday admits that use of these whitening elements may be non-ideal, these elements are used because they are readily available, and optical instruments are known to comprise filtering means to correct the possible resultant noise, and further the noise may or may not have significance in the white balance process [col. 11, Il. 11-26]. Gunday further teaches that frequent white balancing is recommended during changes made to the system [col. 10, II. 15-31]. Since Beane teaches a system already containing an element comprising material capable of being used for white balancing as taught by Gunday, and it is also known to white balance the optical system when any changes occur (e.g. removal of optical instrument from body lumen and insertion into the warmer of Beane is considered a change to the system), it would have been obvious to one of ordinary skill to use element 116 of Beane as a whitening element as taught by Gunday to achieve the predictable result of enabling white balancing of the optical instrument and providing more accurate imaging capabilities with no added design.

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- 6. Regarding claim 3, Beane teaches said apparatus is constructed from a thermoplastics type material [par. 0061].
- 7. Regarding claim 4, Beane teaches said apparatus is constructed from a thermoset plastics material [par. 0061].

8. Regarding claim 7, Beane teaches said heating element comprises a conductive material [par. 0057].

- 9. Regarding claim 8, Beane teaches said conductive material is water or saline solution [par. 0057, e.g. water].
- 10. Regarding claim 10, Beane teaches said whitening element is constructed from one of a group consisting of a thermoset plastics material, thermoform plastics material, ceramics material, non-woven material and woven fibrous material [par. 0061, cotton is a woven fibrous material].
- 11. Regarding claim 11, Beane teaches said heating element is considered capable of being heated prior to use by micro-waving said apparatus.
- 12. Regarding claim 12, Beane teaches said heating element is considered capable of being heated prior to use by inserting said apparatus into a conventional oven type surgical warmer.
- 13. Regarding claim 14, Beane teaches said apparatus is disposable. Anything is capable of being thrown away, thus the apparatus is considered inherently disposable.
- 14. Regarding claim 15, Beane teaches said tube has an attachment mechanism [162] attached to said upper surface configured to removably attach said apparatus to a surgical drape or table [par. 0066].
- 15. Regarding claim 16, Beane teaches said attachment mechanism is a handle [Fig.2D, 162 can be used as a handle].

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16. Regarding claim 20, see rejection of claim 1 above, which contains the same subject matter.

- 17. Regarding claim 26, see rejection of claim 1 above. Use of the Beane device comprises inserting the distal portion of the optical instrument into the device, heating the heating element to warm the device, and the combination of Beane and Gunday teaches calibration via the whitening element.
- 18. Regarding claim 27, Beane teaches heating the heating element comprises raising the temperature of said heating element to a body above ambient body temperature [par. 0010].
- 19. Regarding claim 28, see rejection of claim 27 above.
- 20. Regarding claim 29, the process of white balancing is known in the art to comprise light reflectance off a whitening element into the lens of the optical instrument [Gunday, col. 11, II. 16-24].
- 21. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beane in view of Gunday, as applied to claim 1 above, in view of Agarwal et al. (US 2003/0124277 A1).
- 22. Beane in view of Gunday teaches an apparatus to calibrate an optical instrument and warm a distal portion of said optical instrument according to claim 1, but fail to specifically teach wherein said conductive material is selected from a group consisting of wheat, barley, oat grass seeds and rice. Beane does teach that the heating element [120], which is an exothermic heater, can be substituted with other types of heating

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invention as specified in the claim(s).

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elements [oar. 0067]. Agarwal teaches seed-type products, like rice, are commonly known thermal agents, which are advantageous alternatives to exothermic compositions because they are natural and safe and conform to the space in which they are placed [par. 0067]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute the heating element as taught by Beane with rice as taught by Agarwal in order to provide the advantage of safety. Further, Agarwal teaches seed-type products as thermal agents can retain heat by heating from external sources (e.g. microwave, oven). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the heating element as taught by Beane with the rice as taught by Agarwal, because Applicant has not disclosed that particular type of heating element provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the heating element as taught by Beane, because it provides thermal transfer and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Beane. Therefore, it would have been an obvious matter of design choice to modify Beane to obtain the

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- 23. Claims 2, 5, 13, 18 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beane in view of Gunday, as applied to claims 1 and 20 above, in view of Mukaida (US 6789644 B2).
- 24. Regarding claim 2, Beane (in view of Gunday, although only Beane here is mentioned as it regards structure) teaches the apparatus further comprises a cylindrical

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tube forming part of said heat conducting tube [112] having an external wall [labeled 112 in Fig. 2B], upper surface [entire outer surface of external wall of apparatus] and open distal portion [Fig. 2C, top of 112 labeled in Figure as 118] with central cavity [interior space of 112 in which 120 lies] there between, an aperture [defined by the space of the central cavity] extending from said upper surface sized and shaped to receive said distal portion of said optical instrument, a cap [118] sized to attach to said distal portion of said cylindrical tube, a heating element [120] enclosed within said central cavity wherein said whitening element [116] is located in the distal portion of said aperture [Figs. 2A & 2C], such that said distal portion of said optical instrument abuts said whitening element and light from said optical instrument is capable of being reflected off said whitening element back to said optical instrument in order to achieve white balancing of said optical instrument [par. 0064]. However, Beane fails to specifically teach a double walled cylindrical tube having an internal wall, external wall and an insulation layer between the internal and external walls, or the heating element being thermally coupled to said insulation layer. Mukaida (US 6789644 B2) teaches it is commonly known that double wall constructions comprising an insulation layer in between [Fig. 3, between 14a, 14b] enhance heat insulating efficiency to decrease the heat transfer toward the outside placed double-wall construction [col. 6, Il. 50-60]. Since Beane teaches a heater than is intended to be grasped by a user, it would have been obvious to one of ordinary skill to modify the cylindrical tube with a double wall construction and insulating layer as taught by Mukaida to provide the advantage of enhancing heat insulating efficiency to decrease the heat transfer toward the outside

placed double-wall construction and further, to achieve the predictable result of protecting the user's hand.

- 25. Regarding claim 5, Beane teaches said double walled cylindrical tube has a horizontal cavity [e.g. slits 144a,b] extending from said external wall through said distal portion of said aperture, sized and shaped to fit said whitening element.
- 26. Regarding claim 13, Beane in view of Gunday in view of Mukaida teaches said insulation layer comprises air [Mukaida, col. 6, II. 50-60].
- 27. Regarding claim 18, Beane in view of Gunday in view of Mukaida teach the device of claim 2, but fails to teach said aperture having a flexible grommet surrounding at least a portion of said upper surface adaptable to receive said distal portion of an optical instrument of differing size in the same embodiment. However, Beane teaches another embodiment of the invention as a cannula device with a cylindrical tube [616] having the same function, and many of the same components of the prior embodiment that can be seen in Fig. 6A. This embodiment comprises a flexible grommet [620] surrounding a portion of said upper surface [interpreted as external surface of 616, onto which 612 is attached] to provide the advantage of removing fluid from the shaft of the optical instrument as it is either inserted or removed from the apparatus [par. 0089]. Therefore, it would have been obvious to one of ordinary skill in the art to modify the embodiment as taught by Beane with a flexible grommet to provide the advantage of removing fluid from the shaft of the optical instrument as it is either inserted or removed from the apparatus.

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28. Regarding claims 21-25, see rejections of claims 2 and 5 above, which contain the same subject matter.

### Response to Arguments

29. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Although Applicant argued the non-usability of element 116 of Beane as a whitening element, the examiner found new reference Gunday, which teaches the use of such elements as commonly known whitening elements. The obviousness reasoning is seen in the above rejections.

#### Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 7764304 B2	USPAT	Meron; Gavriel et al	. Method for activating an image collecting process
US 6141037 A	USPAT	Upton; Wayne et al	Video camera system and related method
US 5880779 A	USPAT	Rhynes; Vincent	Sterile disposable white balance box
US 5365267 A	USPAT	Edwards; Nelson	White balance target

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA CHEN whose telephone number is (571)272-3356. The examiner can normally be reached on Monday to Friday, 9AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victoria W Chen/ Examiner, Art Unit 3779 /John P Leubecker/ Primary Examiner, AU 3779 Application/Control Number: 10/599,584

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